Claims

1. A formulation for oral administration comprising an antifungal, a sufficient amount of a cyclodextrin or a derivative thereof, an aqueous acidic medium as bulk liquid carrier and an alcoholic co-solvent.

2. A formulation according to claim 1 further comprising one or more pharmaceutically acceptable sweeteners and one or more pharmaceutically acceptable flavours.

3. A formulation according to claim 1 or 2 wherein the antifungal is itraconazole or saperconazole and the cyclodextrin is hydroxypropyl-β-cyclodextrin having an M.S. in the range of 0.35 to 0.50 and containing less than 1.5% unsubstituted β-cyclodextrin.

4. A formulation according to claim 3 wherein the alcoholic co-solvent is propylene glycol.

5. A formulation according to claim 4 having a pH of 2.0 ± 0.1.

6. A formulation according to claim 5 wherein the pharmaceutically acceptable sweetener comprises at least one intense sweetener and optionally a bulk sweetener.

7. A formulation according to claim 6 wherein the intense sweetener is selected from the group consisting of saccharin, sodium or calcium saccharin and the bulk sweetener is selected from the group consisting of sorbitol, mannitol, fructose, sucrose, maltose, glucose, caramel or honey.

8. A formulation according to claim 2 comprising by weight or by volume based on the total volume of the formulation :

(a) 4% (w/v) itraconazole;
(b) 60% (w/v) hydroxypropyl-β-cyclodextrin;
(c) 10% (v/v) propylene glycol;
(d) acid and base to adjust the pH of the composition within the range of 2.0 ± 0.1;
(e) 0.08% (w/v) sodium saccharin;
(f) up to 1% (w/v) of one or more flavours; and
(g) water.

9. A formulation according to claim 2 comprising by weight or by volume based on the total volume of the formulation :

(a) 1% (w/v) itraconazole or saperconazole;
(b) 40% (w/v) hydroxypropyl-β-cyclodextrin;
(c) 10% (v/v) propyleneglycol;
(d) acid or base to adjust the pH of the composition within the range of 2.0 ± 0.1;
(e) 0.06% (w/v) sodium saccharin;
(f) 19% (v/v) sorbitol (70%) non-crystallizing solution;
(g) up to 1% (w/v) of one or more flavours;
(h) 0.02% (w/v) of a caramel sweetener; and
(i) water.

10. A process of preparing a formulation as claimed in claim 1, characterized in that said process comprises the steps of :

(a) dissolving the active ingredient in the alcoholic co-solvent and acid;
(b) dissolving the cyclodextrin in water and adding thereto the solution prepared in (a) while stirring until homogenous;
(c) adding the sweetener(s) and the flavour(s), if any;
(d) adjusting the acidity to pH 2.0 ± 0.1 and
(e) diluting the formulation to the desired end-volume.